

IN THE UNITED STATES PATENT OFFICE

Applicants: Paul A. Spence et al.
Serial No.: 10/695,380
Filed: October 28, 2003
Art Unit: 3738
Examiner: William H. Matthews
Conf. No.: 5321
Title: HEART VALVE REPAIR APPARATUS AND METHODS
Atty Docket No.: SPEN-03C

DECLARATION BY PAUL A. SPENCE, M.D. UNDER 37 C.F.R. § 1.132

I, PAUL A. SPENCE, hereby stated and declare the following:

I am named as an inventor in the above-captioned U.S. patent application (the '380 application) disclosing various forms of heart valve repair apparatus and methods of their use. My medical background, including my education, practical experience, publications and other relevant information are summarized in the attached Curriculum Vitae (Exhibit A).

As Exhibit B, I have attached a published diagram that accurately depicts the normal anatomy of the heart and, particularly, the mitral valve and adjacent structure of the heart. This diagram is consistent, for example, with Figs. 2 and 24 in the '380 patent application. In this regard, the mitral valve as shown in Exhibit B is located at the top of the left ventricle alongside the aortic valve. This is also shown in Fig. 2 of the '380 patent application. The outer wall of the heart is shown in Exhibit C adjacent to the posterior leaflet of the mitral valve, as is wall 12a in Fig. 2. The aortic valve is shown in Exhibit B on the opposite side of the mitral valve from the outer wall of the heart as also shown in Fig. 2 of the '380 patent application. In a similar manner, Fig. 24 of the '380 application shows the outer wall 12a of the heart, and the papillary muscle 24 which has

been severed in the same manner as shown in Fig. 2 of the '380 application. This is consistent with the anatomy of the heart as shown in Exhibit B and supports the amendments made to the specification and drawings to explicitly set forth which valve leaflet is the "anterior" leaflet and which valve leaflet is the "posterior" valve leaflet. As further shown in the top view of Exhibit C, the anterior leaflet and posterior leaflet (or cusps) meet at a junction which is generally curved as shown, for example, in Figs. 2 and 23 of the '380 patent application. The anterior leaflet is larger than the posterior leaflet and is on the concave side of the curved junction between the leaflets. For these reasons, the modifications made to Figs. 2 and 22-24 are fully consistent with the actual anatomy of the heart and one of ordinary skill in the art of mitral valve repair would readily understand that the changes made to the drawing figures and the corresponding changes to the written specification of the '380 application providing further explanation of the drawing figures are consistent and accurate depictions of actual heart anatomy as originally disclosed in the '380 application upon filing. From a review of, for example, Exhibit C and specifically the top view of the mitral valve in the lower diagram of Exhibit C, compared to the corresponding view of Fig. 23 from the '380 patent application, the mitral valve annulus is generally "D" shaped with a substantially straight portion extending along the anterior cusp or leaflet and a generally curvilinear portion extending along the posterior cusp or leaflet. This is also evident in Fig. 2 of the '380 patent application.

As shown in Fig. 24 of the '380 patent application, when a posterior portion of device 370 is formed in a nonplanar fashion and then affixed to the valve annulus posterior portion 376b as shown, the valve annulus will be forced into a position

according to the three-dimensional shape of the device 370. Thus, the vertical position of the annulus at that posterior location will be modified as compared to its natural position.

Further Declarant sayeth not.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true, and further that these statements were made with knowledge that willful false statements and the like, so made, are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the patent application or any patent issued thereon.

June 22/06
Date

Paul A. Spence
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CURRICULUM VITAE
PAUL A. SPENCE, M.D.

Residential Address:	5818 Orion Road Louisville, Kentucky 40222	
Education:	Queen's University Faculty of Arts & Science Kingston Ontario, Canada	1974-1976
	Queen's University Medical School Kingston Ontario, Canada M.D. Degree	1976-1980
	University of Toronto Toronto, Ontario, Canada M.Sc. Degree	1983-1986
Internship:	McGill University Royal Victoria Hospital Montreal, Quebec, Canada	1980-1981
Residency:	University of Toronto General Surgery	1981-1986
	University of Toronto Cardiovascular & Thoracic Surgery	1986-1988
Academic Appointments:	Associate Professor of Surgery Department of Cardiac Surgery East Carolina University School of Medicine Greenville, North Carolina	1988-1992
	Associate Professor of Surgery Department of Surgery Division of Thoracic & Cardiovascular Surgery University of Louisville Louisville, Kentucky	1992-1999

	Professor of Surgery	1999 -2000
	Department of Surgery	
	Division of Thoracic & Cardiovascular Surgery	
	University of Louisville	
	Louisville, Kentucky	
	Clinical Professor	2000 - 2004
	Department of Surgery	
	Division of Thoracic & Cardiovascular Surgery	
	University of Louisville	
	Louisville, Kentucky	
Current Position:	Medical Device Investment Advisor	
	Accelerated Technologies Inc	
	Hackensack, NJ	
Medical Licenses:	North Carolina #32873	1988
	Kentucky #29237	1992
Certifications:	American Board of Surgery	1987
	American Board of Thoracic Surgery	1989
	FRCS (C) General Surgery	1986
	FRCS (C) Cardiovascular & Thoracic Surgery	1988
Professional Organizations:	American Medical Association	
	American College of Surgeons	
	American College of Cardiology	
	American Heart Association (Council on Circulation)	
	Association for Academic Surgery	
	Academy of Surgical Research	
	Southern Thoracic Surgical Association	
	Fellow of Royal College of Surgeons of Canada	
	Sigma Xi	
	European Association for Cardio-Thoracic Surgery	
	Society of Thoracic Surgeons	
	Southern Thoracic Surgical Society	
Hospital Committees:	University of Louisville	
	Surgery Representative to Faculty Forum	1993-1995
	Physician Quality Improvement Committee	1994-1995

Jewish Hospital

Critical Care Committee	1993-1994
Infectious Control Committee	1993-1994
Heart & Lung Institute	1993-1994
H/L Publication Advisory Committee	1997-1998

Baptist East Hospital

Intensive Care Committees	1993-1996
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Honors & Awards:

Tricolour Scholarship	1974-1976
Queen's University	
Edgar Forrester Scholarship	1976-1980
Murphy Memorial Scholarship	1976-1980
N.F. Dupuis Scholarship	1976-1977
Dr. Ernest C. Armstrong Prize	1977-1978
Mosby Book Prize for Pathology	1977-1978
W.G. Anglin Scholarship in Surgery	1978-1979
Victor Lyall Goodwill Scholarship in Internal Medicine	1978-1979
Ratray Scholarship in Ophthalmology	1978-1979
W.W. Near & Susan Near Prize	1979-1980
The Professor's Prize in Obstetrics & Gynecology	1979-1980
Bryan George Blair Memorial Prize	1979-1980
Neil Currie Polson Memorial Prize	1979-1980
Frederick Boyd Prize	1979-1980
Medical Research Council of Canada Fellowship	1983-1984
Medical Research Council of Canada Fellowship	1984-1985
Young Investigator Award - Canadian Cardiovascular Society	1984-1985

Journals:

<i>Current Surgery</i> - Executive Editor	1989-1992
<i>Current Surgery</i> - International Editor	1989-Present
<i>Annals of Thoracic Surgery</i> - Guest Reviewer	1990-Present
<i>Chest</i> - Guest Reviewer	1991-Present
<i>Journal of Thoracic and Cardiovascular Surgery</i> - Guest Reviewer	1990-Present

PUBLICATIONS: Peer-reviewed

1. **Spence PA**, Morin JE, Katz M: The role of plasmapheresis in preparing myasthenic patients for thymectomy: initial results. *Canadian Journal of Surgery*, 26:303-305, 1984.
2. McGregor M, Sheldon H, Dwyer D, Stefaniszyn HJ, Novick RJ, **Spence PA**, Salerno TA: The role of intimal hyperplasia in arterial spasm. *Canadian Medical Association Journal*, 131:329-330, 1984.
3. **Spence PA**, Weisel RD, Easdown J, Jabr K, Yav V, Salerno TA: Pulmonary artery balloon counterpulsation and its mechanism of action in right ventricular failure during left heart bypass. *Surgical Forum*, 35:325-326, 1984.
4. **Spence PA**, Cohen Z, Salerno TA: Strangulated diaphragmatic hernia in a patient with osteogenesis imperfecta. *Canadian Medical Association Journal*, 131:1369-1370, 1984.
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7. **Spence PA**, Mathews RE, Khanna R, Oreopoulos DG: Improved results with a paramedian technique of peritoneal dialysis catheter insertion. *Surgery, Gynecology & Obstetrics*, 161:585-587, 1985.
8. **Spence PA**, Weisel RD, Easdown J, Jabr K, Yap V, Salerno TA: The hemodynamic effects and mechanism of action of the pulmonary artery balloon counterpulsation in the treatment of right ventricular failure during left heart bypass. *Annals of Thoracic Surgery*, 39:329-335, 1985.
9. **Spence PA**, Mathews RE, Khanna R, Oreopoulos DG: When should laparotomy be performed for peritonitis in chronic ambulatory peritoneal dialysis patients? *Surgery, Gynecology & Obstetrics*, 161:450-452, 1985.
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11. **Spence PA**, Peniston CM, Mihic N, Jabr AK, Narini P, Salerno TA: An assessment of left ventricular function after mitral valve replacement: the effects of division of the chordae tendineae and fixation of the mitral annulus. *Surgical Forum*, 36:236-237, 1985.

12. **Spence PA**, Weisel RD, Salerno RA: Right ventricular failure pathophysiology and treatment. *Surgical Clinics of North America*, 65:689-397, 1985.
13. **Spence PA**, Peniston CM, David TE, Mihic N, Jabr AK, Narini P, Salerno TA: Towards an understanding of the etiology of left ventricular dysfunction after mitral valve replacement -- an experimental study in pigs with possible clinical implications. *Annals of Thoracic Surgery*, 41:463-471, 1986.
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15. **Spence PA**, Peniston CM, Mihic N, David TE, Jabr AK, Archer D, Salerno TA: A physiologic approach to surgery for acute rupture of the papillary muscle. *Annals of Thoracic Surgery*, 42:27-30, 1986.
16. **Spence PA**, Peniston CM, Jabr AK, Salerno TA: A rational approach for the selection of a mechanical assist device for the failing right ventricle. *Annals of Thoracic Surgery*, 41:606-608, 1986.
17. Sun YS, Lust RM, **Spence PA**, Iida H, Pollock SB, Williams JM, Austin EH: Spinal cord protection by balloon occlusion of the distal aorta during proximal aortic cross clamping. *Surgical Forum*, 41:274-275, 1989.
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25. **Spence PA**, Naylor DN: Statistical analysis of surgical results: A look at outcome-based research. *Current Surgery*, 48:581-582, 1991.
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48. Cerrito P, Koenig SC, Van Himbergen DJ, Jaber S, Ewert DL, BhaskerRao B, and **Spence PA**. Neural Network Pattern Recognition Analysis of Graft Flow Characteristics Improves Intra-Operative Anastomotic Error Detection in Minimally Invasive CABG. *Eur. J. Cardiothoracic Surg*. 16:88-93, July 1999.

49. Koenig SC, VanHimbergen DJ, Jaber SF, Ewert DL, Cerrito P, **Spence PA**. Spectral analysis of graft flow for anastomotic error detection in off-pump CABG. *Eur J. Cardiothoracic Surg.*, 16:S84-S87, August 1999.
50. VanHimbergen DJ, Koenig SC, Jaber SF, Cerrito PB, **Spence PA**. A review of transit time flow measurement for assessing graft patency. *Heart Surgery Forum*, 2:226-229, 1999.
51. Pagni S., Bousamra M., Shirley MW., **Spence PA**. Successful VATS ligation of a large anomalous branch producing IMA steal syndrome after MIDCAB. *Ann Thorac Surg.* 71(5):1681-2, 2001, May.

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1. **Spence PA**, Bayliss C, Peniston CM, Salerno TA: Right ventricular failure associated with left heart failure. *Cardiovascular Clinics*, 17:239-249, 1987.
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4. VanHimbergen DJ, Jaber SF, Koenig SC, Kashem MA, Bhasker Rao B, **Spence PA**. A new technique to create an artificial stenosis in the native LAD using a hemoclip. *J. Invest. Surg.*, 13:7-13, January 2000.

ABSTRACTS PUBLISHED

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4. **Spence PA**, Peniston CM, Mihic N, Jabr AK, Narini P, Salerno TA: The effects of division of the chordae tendineae and fixation of the mitral annulus on left ventricular function after mitral valve replacement. *Clinical & Investigative Medicine*, A52:1985.

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6. Peniston CM, **Spence PA**, Mihic N, Jabr AK: Atrial dysfunction after cardioplegic arrest. *Circulation*, 72 (Supplement III):375, 1985.
7. Iida H, Sun YS, Lust RM, **Spence PA**, Pollock SB, Williams JM, Austin EH: Aortic root angiography after cardiac arrest. *Journal of Investigative Surgery*, 2:325, 1989.
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9. Sun YS, Lust RM, Iida H, **Spence PA**, Austin EH: A reappraisal of the mechanism for CSF hypertension during aortic surgery. *Circulation*, (Supplement II):225, 1989.
10. **Spence PA**, Lust RM, Chitwood WR Jr, Iida H, Sun YS, Austin EH: Transfemoral balloon aortic occlusion during open cardiopulmonary resuscitation improves myocardial and cerebral blood flow. *Circulation*, (Supplement II):80:495, 1989.
11. **Spence PA**: Prevention of infection in cardiovascular surgery. *Current Surgery*, 48:131, 1991.
12. Montgomery WD, **Spence PA**, Hansen SB, Gray AL, Santamore WP: A model to study arterial bypass graft vasoreactivity. *Journal of Investigative Surgery*, 74:362, 1994.
13. Montgomery WD, **Spence PA**, Sinai K, Santamore WP: Mechanism of spasm in gastroepiploic artery bypass grafts. *Clinical Research*, 42(3):475A, 1994.
14. Zeri RS, Lust LM, **Spence PA**, Hopson SZ, Sun YS, Otaki M, Jolly SR, Mehta PM, Chitwood WR: The effects of chronic competitive flow from a fully patent coronary artery on thoracic artery grafts. *Ann of Thorac Surg* 57: 45-50, 1994.
15. Driver AG, Kukoly C, **Spence PA**, Chitwood WR, Mustafa SJ: Pericardial fluid adenosine in ischemic and valvular heart disease. *Chest* 107:346, 1995.
16. BhaskerRao B, VanHimbergen D, Edmonds HL, Jaber Saad, Ali AT, Pagni S, Koenig S, **Spence PA**: Evidence for Improved Cerebral Function After Minimally Invasive Bypass Surgery. *Jour Card Surg* 13, (1):27-31, 1998.
17. Singer I, Dawn Buddhadeb, Calzada N, **Spence PA**: Atrial Fibrillation: A Delayed Presentation of Traumatic Tricuspid Valve Incompetence. *Cardiology* Vol 89#4, May 1998.
18. Prabhune A, Sehic A, Spence, PA, Church T, Edmonds, HL. "Cerebral Oximetry Provides Early Warning of Oxygen Delivery Failure During Cardiopulmonary Bypass". *Journal of Cardiothoracic and Vascular Anesthesia*. Vol 16, 2 (April) 204-206, 2002.

BOOK CHAPTERS

1. Peniston CM, **Spence PA**, Archer D, Jabr AK, David TE, Salerno TA: Does the size of the prosthesis affect global ventricular function following mitral valve replacement. Proceeding of the World Conference on Open Heart Surgery, 1985.
2. **Spence PA**, Peniston CM, Weisel RE, Easdown J, Jaber AK, Yap V, Salerno TA: Right heart failure during left heart bypass: the role of pulmonary artery balloon counterpulsation. Proceeding of the World Conference on Open Heart Surgery, 1985.
3. Peniston CM, El-Dalati H, **Spence PA**, Salerno TA: The significance of arterial cooling and electrical inactivity in myocardial protection. Chapter 26 in *Myocardial Protection in Cardiac Surgery*, ed. Arthur J. Roberts, Dekker, 1987.
4. Wittnich C, **Spence PA**, Salerno TA: Pulmonary artery balloon counterpulsation for right heart failure. *Counterpulse*, 1991.
5. Lattouf OM, Jabr AK, **Spence PA**. Pitfalls in warm oxygenated blood cardioplegia. *Warm Heart Surgery*. Arnold, 1995.
6. Cerrito P., Koenig SC., **Spence PA**. Automated classification procedures and neural network models to predict the level of anastomotic stenosis in off-pump CABG surgery. Chapter 8: In Intraoperative graft patency verification in cardiac and vascular surgery. Futura Publishing Company, Armonk, NY., May 2001.

EDITORIALS, SPECIAL ARTICLES AND BOOK REVIEWS

1. **Spence PA**,: New approaches to aortic valve surgery [review]. *Current Surg* 51:359-60, 1994.
2. **Spence PA**: Editorial: A careful operation. *Current Surgery*, 48:131, 1991.
3. **Spence PA**: Editorial: Medical new from around the world. *Current Surgery*, 47:56, 1991.
4. **Spence PA**: Editorial: Further thoughts on laparoscopic intervention. *Current Surgery*, 48:631, 1991.
5. **Spence PA**, Lust RM, Ruiz V: Operative strategy and techniques. *State of the Art Reviews*, 5:3, 1991.

ARTICLES SUBMITTED

1. Otaki M, Lust RM, Norton TO, Sun YS, **Spence PA**, Chitwood WR Jr: Extracardiac adjustment of mitral chordae replacement. Submitted *Journal of Surgical Research*.
2. Montgomery WD, **Spence PA**, Riordan CJ, Storey JH, Santamore WP: An evaluation of the duration of effectiveness of vasodilators on intact porcine ITA and GEA bypass grafts. Submitted *European Journal of Cardiothoracic Surgery*.
3. Cerrito P, Koenig SC, VanHimbergen DJ, Jaber S, Ewert DL, Bhasker-Rao B, Spence PA: Neural Network Pattern Recognition Analysis of Graft Flow Characteristics Improves Intra-operative Anastomotic Error Detection in Minimally Invasive CABG. *Eur J. Cardiothoracic Surg*.

PRESENTATIONS

1. **Spence PA**, Morin JE, Katz M: Plasmapheresis in Preparation for Thymectomy. *Surgical Grand Rounds*. Royal Victoria Hospital, McGill University, Montreal, November 1982.
2. **Spence PA**, Mathews PE, Kanna R, Oreopoulos DG: When Should Laparotomy be Performed for Peritonitis in Chronic Ambulatory Peritoneal Dialysis Patients. *Annual Assembly of General Surgeons*, University of Toronto, May 1984.
3. **Spence PA**, Easdown J, Jabr AK, Weisel RD, Salerno TA: The Hemodynamic Effects and Mechanism of Action of Pulmonary Artery Balloon Counterpulsation in the Treatment of Right Ventricular Failure During Left Heart Bypass. *Gallie Day Competition*, University of Toronto, May 1984.
4. **Spence PA**, Easdown J, Jabr AK, Salerno TA: Pulmonary Artery Balloon Counterpulsation for the Failing Right Ventricle. *European Society of Cardiology*, Dusseldorf, Germany, July 1984.
5. **Spence PA**, Jabr AK, Yap V, Salerno TA: Limitations on the Capacity of the Systemic Circulation to Maintain Cardiac Output Without the Participation of the Right Ventricle. *American Physiological Society Annual Fall Meeting*, Lexington, Kentucky, August 1984.
6. Salerno TA, **Spence PA**: Right Heart Assist During Left Heart Bypass. *Strikeman Visiting Professor Meeting*, McGill University, Montreal PQ, May 1984.
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8. **Spence PA**, Weisel RD, Easdown J, Jabr AK, Salerno TA: Pulmonary Artery Balloon Counterpulsation for Right Ventricular Failure During Left Heart Bypass. *Annual Meeting of the Michael DeBakey Society*, Monte Carlo, Monaco, September 1984.
9. **Spence PA**, Weisel RD, Easdown J, Jabr AK, Yap V, Salerno TA: The Hemodynamic Effects and Mechanism of Action of Pulmonary Artery Balloon Counterpulsation in the Treatment of Right Ventricular Failure During Left Heart Bypass. *The Young Investigator Award Address, Annual Meeting of the Canadian Cardiovascular Society*, Quebec PQ, October 1984.
10. **Spence PA**, Weisel RD, Easdown J, Jabr AK, Yap V, Salerno TA: Pulmonary Artery Balloon Counterpulsation and its Mechanism of Action in Right Ventricular Failure During Left Heart Bypass. *Surgical Forum of the American College of Surgeons Clinical Congress*, San Francisco, California, October 1984.

11. **Spence PA**, Weisel RD, Jabr AK, Yap V, Salerno TA: Is Atrial Function Affected by Conventional Cardioplegic Arrest? *Annual Meeting of the Association for Academic Surgery*, San Antonio, Texas, November 1984.
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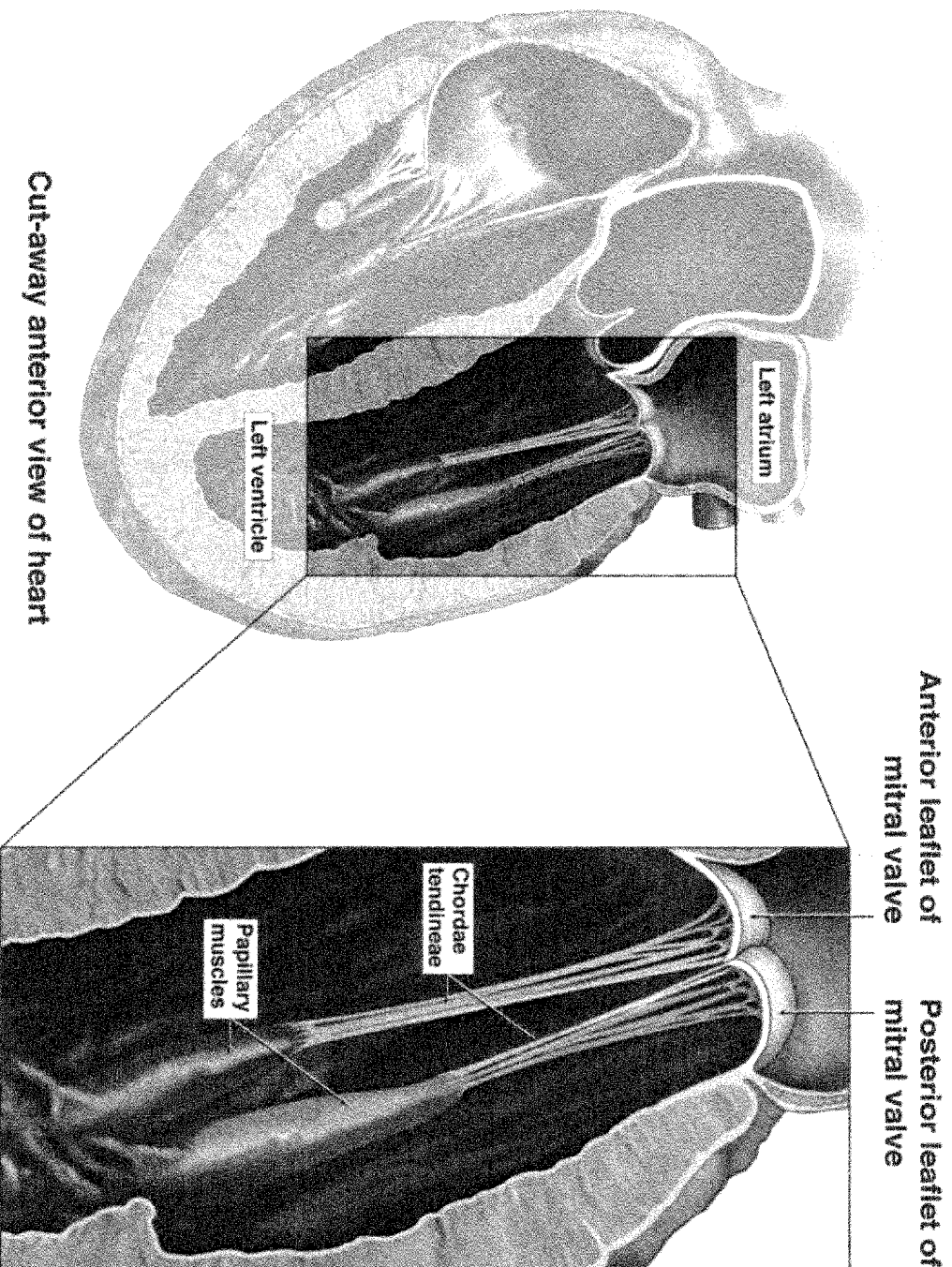
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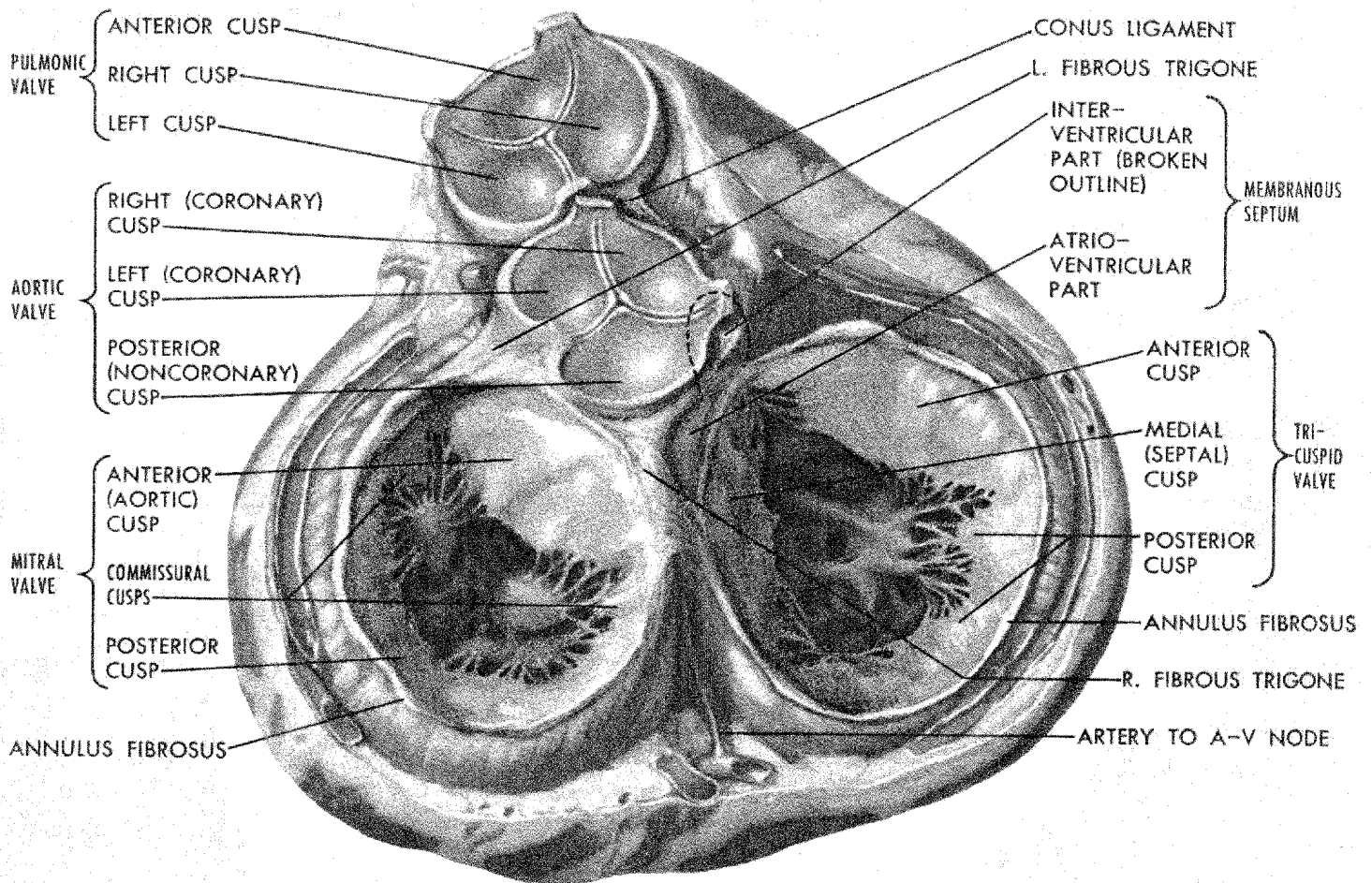
ACADEMIC PRESENTATIONS

1. Acquired Heart Disease. Junior Students, University of Louisville.
2. Arterial Conduits for Coronary Artery Surgery. *Grand Rounds*, Department of Surgery, University of Louisville, March 1993.
3. New Horizons: The Open Beating Heart. Jewish Hospital 2nd Annual Perioperative Symposium. Jewish Hospital, Louisville, KY November 6, 1999.

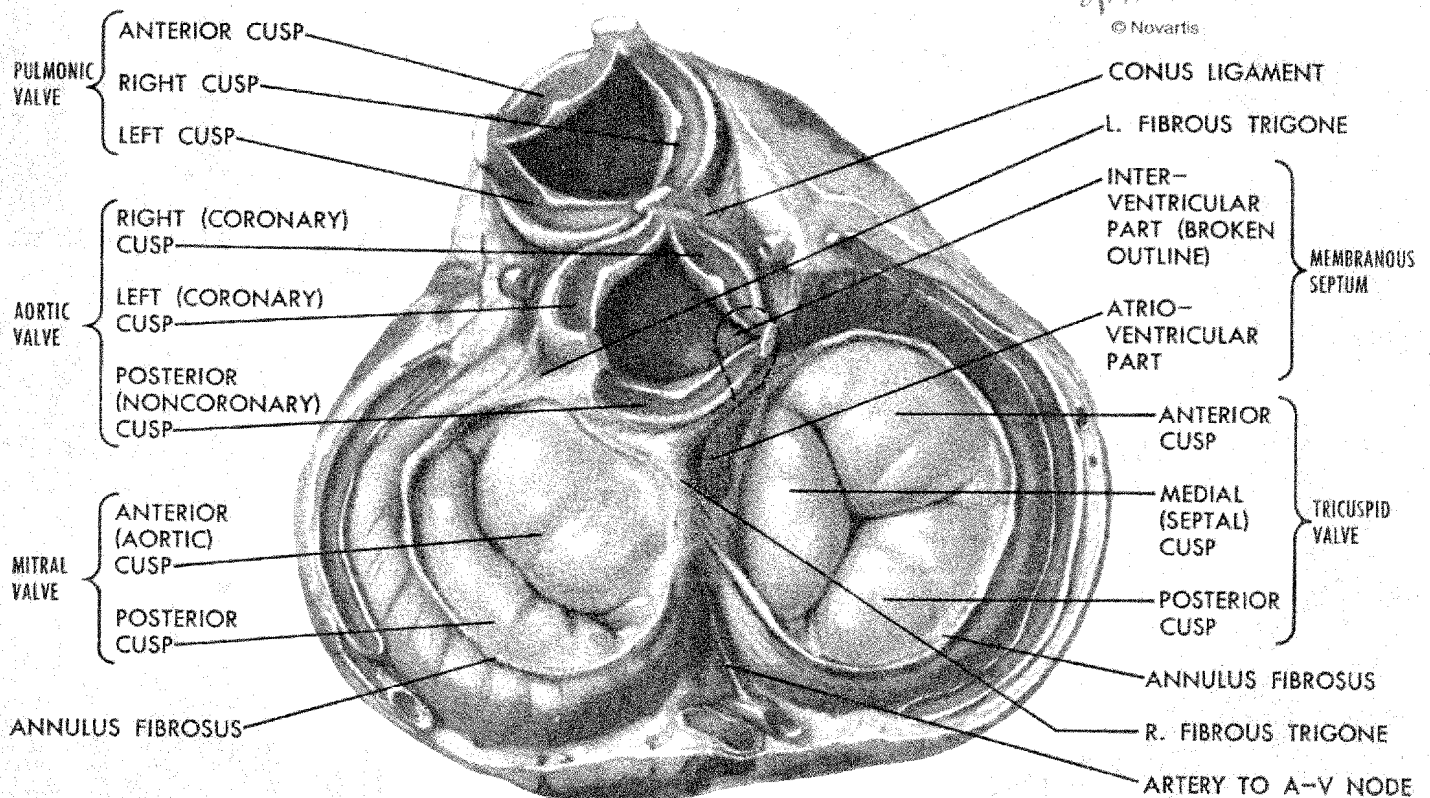
Normal Anatomy of the Mitral (Bicuspid) Valve of the Heart



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THE HEART IN DIASTOLE: VIEWED FROM BASE WITH ATRIA REMOVED



THE HEART IN SYSTOLE: VIEWED FROM BASE WITH ATRIA REMOVED

F. Netter M.D.
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